

513(g) Requests for Information

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I have a product
and I am not sure
if it is a medical
device?

I have a product
and I am not
sure how it is
classified?



What do I do?

Learning Objectives

1. Describe how FDA addresses device determination inquiries
2. Outline the 513(g) Request process
3. Explain when it is appropriate to send an informal device determination email or a formal 513(g) request for information

Definition of a Medical Device

Section 201(h) of the Food, Drug & Cosmetic Act (FD&C Act) defines a device as:

An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory which is:

Definition of a Medical Device

(Continued)

- Recognized in the **official National Formulary**, or the **United States Pharmacopoeia**, or any supplement to them,
- Intended for use in the **diagnosis of disease** or other **conditions**, or in the **cure, mitigation, treatment**, or **prevention of disease** in man or other animals, or
- Intended to **affect the structure or any function** of the body of man or other animals

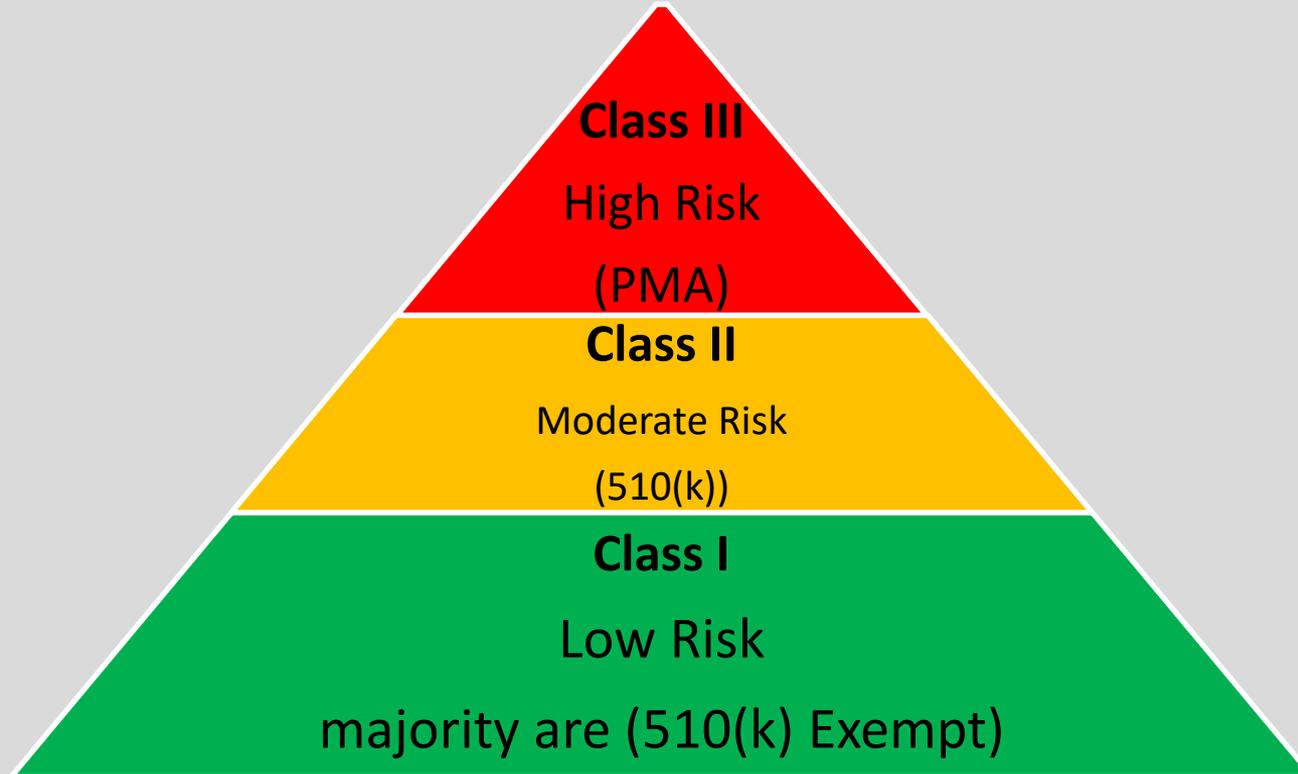
Definition of a Medical Device

(Continued)

- And does **not** achieve its primary intended purposes through **chemical action** within or on the body of man or other animals and which is not dependent upon being **metabolized** for the achievement of its primary intended purposes
- The term "device" does **not** include **software functions excluded pursuant to section 520(o)**

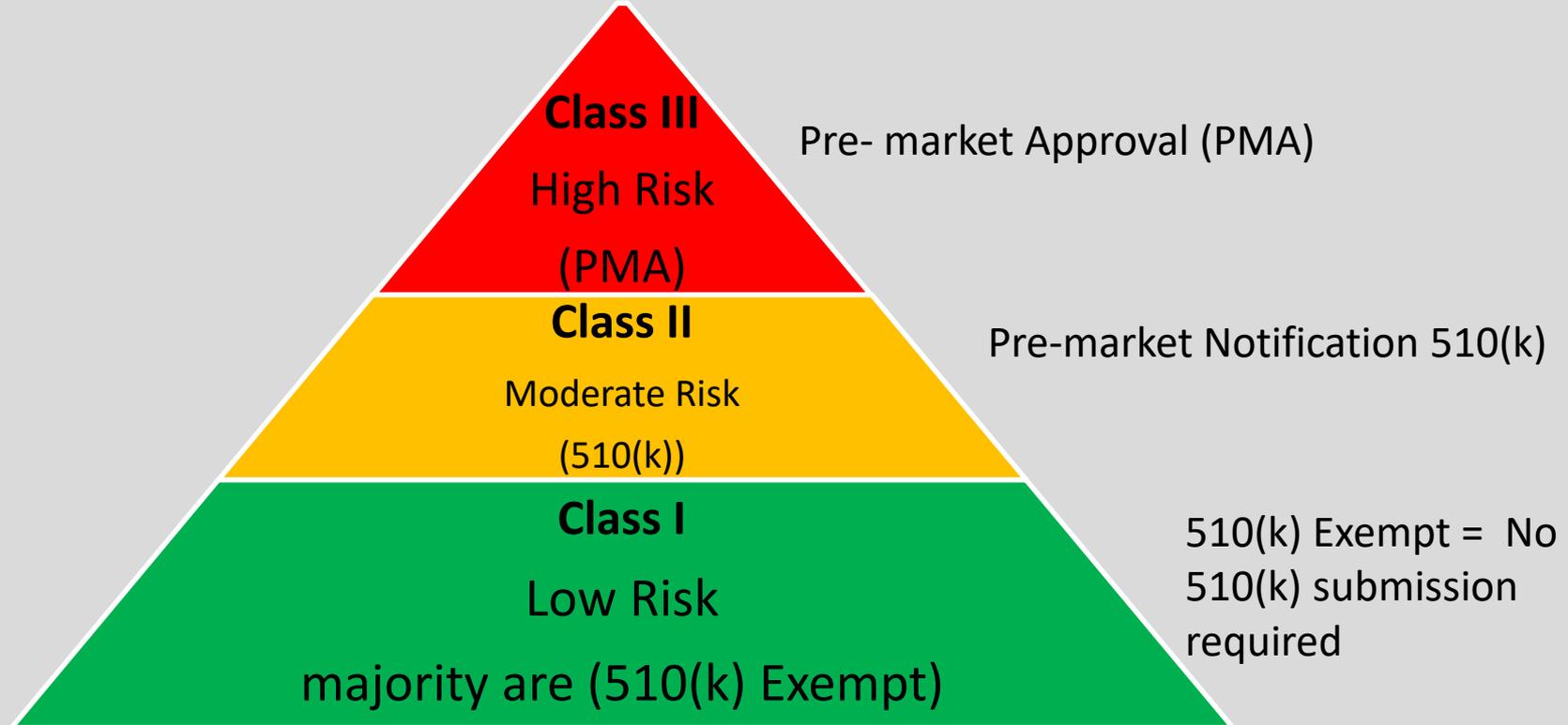
Regulatory Classes

Devices are classified based on level of risk



Regulatory Classes

Devices are classified based on level of risk



De Novo Classification Request (De Novo)

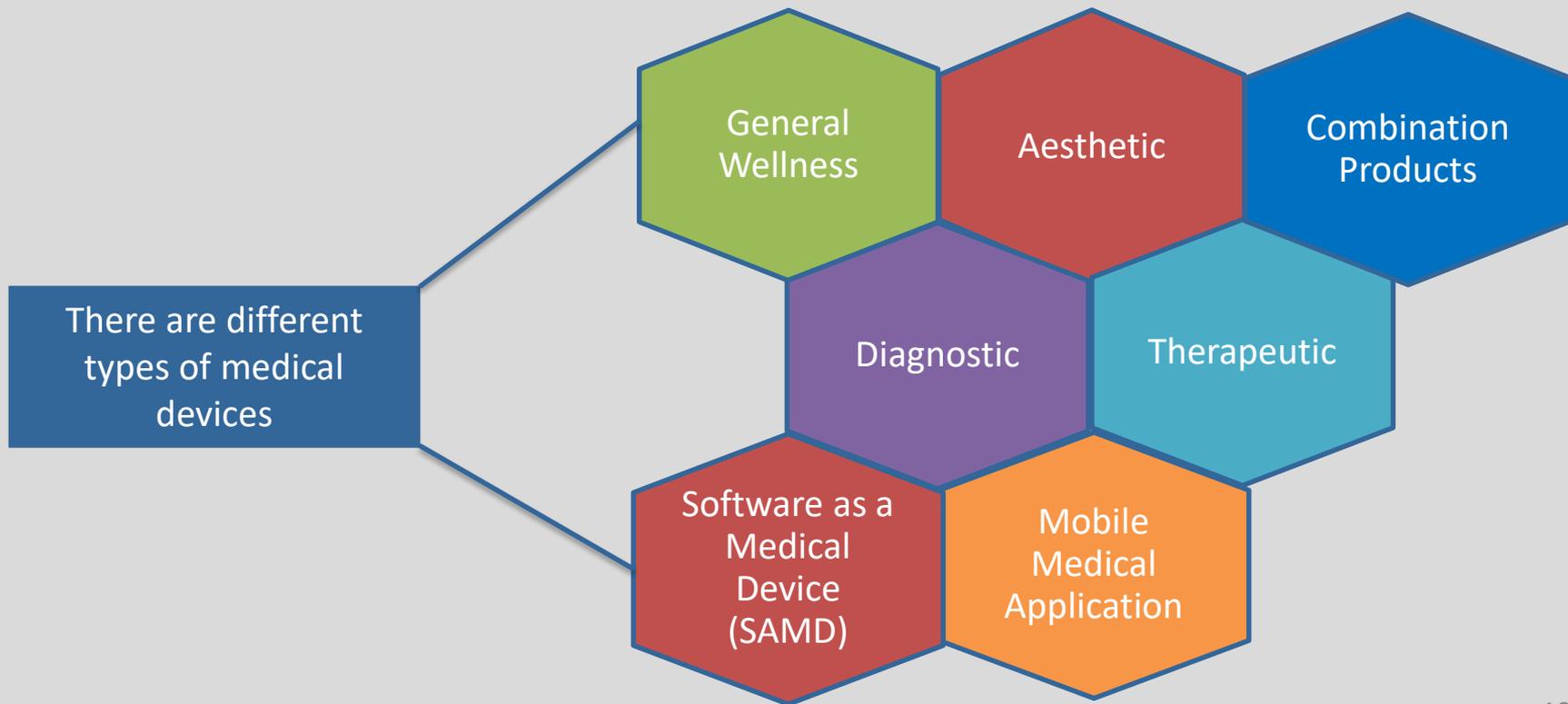


- Automatically been placed in Class III due to lack of an appropriate predicate
- Alternate pathway to classify novel devices of low to moderate risk

[Acceptance Review for De Novo Classification Requests](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-review-de-novo-classification-requests)

www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-review-de-novo-classification-requests

Device Categories



Is My Product A Medical Device?

Your Device Determination Steps

1. Know the intended use and technology of the device. What does it do? How does it do it?
2. Does it meet the definition of a medical device per section 201(h) of the FD&C Act?
3. Check FDA databases for existing or similar device

Still Unsure? Obtain Feedback from Us

Mechanism For Obtaining Feedback

Option 1 - Informal

**Email Device
Determination
Mailbox**

**CDRH provides quick and
informal response**

Option 2 - Formal

**Submit a 513(g)
Request**

**FDA provides formal
response with device
classification if applicable**

Option 1 - Informal Device Determination

- **Email inquiry to Device Determination Team at:**
DeviceDetermination@fda.hhs.gov
- **Include the following information in your email:**
 - Brief device description
 - Clear intended use
 - List or picture of all labeling claims

Example Email Inquiry

- I have a heat pack made of fabric that contains oats
- The pack is heated in the microwave and can be reused
- The heat pack is intended to provide pain relief and increase blood circulation
- Is my product a medical device regulated by the FDA?

CDRH Informal Device Determination Response

- Yes/no response with additional relevant information (e.g. link to regulation or guidance document) when appropriate
- Generally provided within 7 days
- If inquiry is complex and cannot be adequately addressed via email, we may recommend submission of a 513(g) Request

Example Email CDRH Response

- Based on the information you provided, the heat pack product appears to be a medical device per Section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act
- This is our best judgment on how the product would be regulated. **This response is not a classification decision and does not constitute FDA clearance or approval for commercial distribution of a product**

Option 2 - Formal Device Determination 513(g) Request

- Request for classification information and regulatory requirements for a particular product
- Governs requests "for information respecting the class in which a device has been classified or the requirements applicable to the device."

Information to Include in a 513(g) Request

1. Cover Letter
2. Device Description
3. Intended Use
4. Labeling Claims

Guidance: FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act

www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-procedures-section-513g-requests-information-under-federal-food-drug-and-cosmetic

1. Cover Letter

- Date of the request
- Company name
- Contact person
- Contact information (email and phone number)
- Device Name
- Question(s) to FDA

2. Device Description

- Brief description
- Describe mechanism of action
- Describe disease or condition the device is intended for
- Include picture or schematic, if available
- Patient population

3. Intended Use

- Describe what the device is used for
- Physiological purpose

Example: The device is intended for removal of body fat

4. Labeling Claims

- Promotional claims beyond the intended use

Example: Device removes 10% of body fat

Types of 513(g) Questions

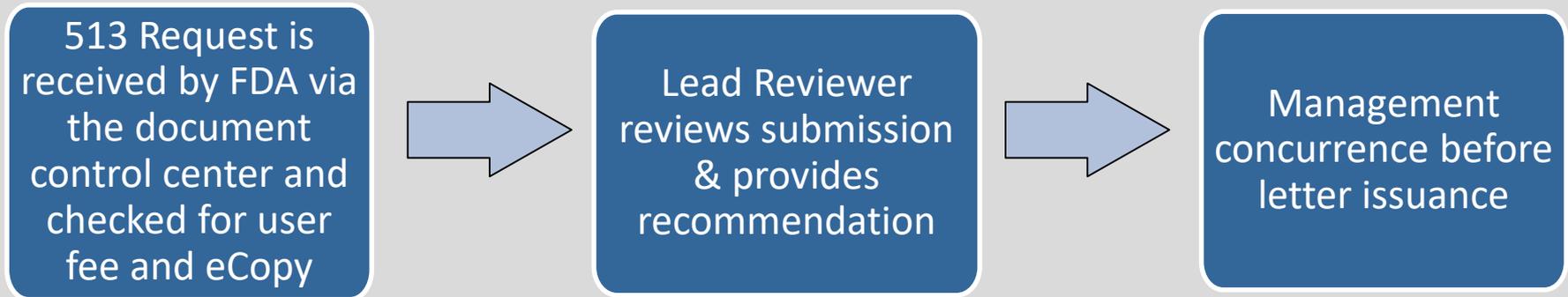
APPROPRIATE

- Is the product subject to FDA regulations?
- What is the appropriate regulatory pathway?
- Is the product exempt from 510(k)?

NOT APPROPRIATE

- Type of performance data required?
- Adequacy of performance data?
- Adequacy of predicate?
- Request for reclassification?

Overview of 513(g) Review Process



FDA User Fee Programs

www.fda.gov/industry/fda-user-fee-programs

eCopy Program for Medical device Submissions

www.fda.gov/medical-devices/how-study-and-market-your-device/ecopy-program-medical-device-submissions

FDA Review 513(g) Request

- All information provided is reviewed by a lead reviewer, who may work with other subject matter experts
- Regulation and precedent set by existing medical devices is considered
- A medical device determination is made for the product based on technology, intended use and medical claims
- If needed additional information is requested
- FDA provides a recommendation and issues a letter via email within 60 calendar days

FDA's Response

- Response via formal letter
- Letter includes:
 - Device determination
 - Device class if applicable (i.e. Class I, II, or III)
 - Indicate whether device is under enforcement discretion, when appropriate
 - Recommended regulatory pathway (e.g. 510(k), exempt, De Novo, etc.)
 - Other applicable information when appropriate (e.g. guidance document)

513(g) Example Letter



EXAMPLE

Pear Company
 % Johnathan Doe
 Consultant
 Medical Device Company, LLC
 121 Apple Bay Court, NE
 Miami, Florida 33704

Re: C191234
 Product Name: Device A
 Dated: May 5, 2019
 Received: May 7, 2019

Dear Johnathan Doe:

We have reviewed the above referenced request for information, submitted in accordance with Section 513(g) of the Federal Food, Drug, and Cosmetic Act (Act), regarding the regulatory requirements applicable to the Device A . Based on the information provided in your submission, we believe that the Device A is an a Heat And Moisture Condenser (Artificial Nose). The Food and Drug Administration (FDA) has classified a Heat And Moisture Condenser (Artificial Nose) as a Class I type device under Title 21 of the Code of Federal Regulations (CFR) 868.5375. A Heat And Moisture Condenser (Artificial Nose) is a Class I type device, exempt from the premarket notification [510(k)] requirements of the Act, subject to the limitations to the exemption found in 21 CFR 868.9.

Responses and Information

- Responses provided via email or 513(g) are recommendations and not binding feedback and does not constitute FDA clearance or approval for commercial distribution of a product
- Stakeholder information provided via the device determination mailbox and 513(g) Request for Information is confidential

References

- **FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act Guidance Document (2012)**
www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-procedures-section-513g-requests-information-under-federal-food-drug-and-cosmetic
- **User Fees for 513(g) Requests for Information Guidance (2017)**
www.fda.gov/regulatory-information/search-fda-guidance-documents/user-fees-513g-requests-information
- **Is a product a medical device? FDA website**
www.fda.gov/medical-devices/classify-your-medical-device/product-medical-device

References

- **General Wellness: Policy for Low Risk Devices Guidance (2016)**
www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices
- **Medical Mobile Application FDA website**
www.fda.gov/medical-devices/digital-health/mobile-medical-applications
- **Software as a medical device FDA website**
www.fda.gov/medical-devices/digital-health/software-medical-device-samd

Providing Industry Education

1. CDRH Learn – Multi-Media Industry Education

- Videos, audio recordings, power point presentations, software-based “how to” modules describing aspects of medical device and radiation emitting product regulations: www.fda.gov/CDRHLearn

2. Device Advice – Text-Based Education

- Text-based resource that explains many aspects of medical device laws, regulations, guidances, and policies:

www.fda.gov/MedicalDevices/DeviceRegulationandGuidance

3. Division of Industry and Consumer Education (DICE)

- If you have a question - Email: DICE@fda.hhs.gov
- Phone: 1(800) 638-2041 or (301) 796-7100 (Live Agents 9a –12:30 pm; 1-4:30 pm EST)

Summary

- A product is considered to be a medical device if it meets the definition in Section 201(h) of the FD&C Act
- There are two mechanisms to receive feedback, email us at device determination or submit a 513(g) request

Your Call To Action

- Search for similar devices in FDA databases
- Email DeviceDetermination@fda.hhs.gov for a simple inquiry
- Submit a 513(g) Request for a complex inquiry and/or if you are seeking device classification
- Refer to the FDA 513(g) Request For Information Guidance for instructions when submitting a 513(g)

